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09/940,273	08/27/2001	Gust H. Bardy	032580.0027.UTL	5279

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/11/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,273

Applicant(s)

BARDY ET AL.

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-219 is/are pending in the application.
- 4a) Of the above claim(s) 1-52 and 137-219 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-75 and 77-136 is/are rejected.
- 7) ☒ Claim(s) 76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I- Species IV in Paper No. 9 is acknowledged.
2. Claims 1-52, and 137-219 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

### *Drawings*

3. The drawings are objected to because in Figure 23 B element number 228 is missing and not shown as it is in Fig. 23A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

4. Claims 64-69, and 106-111 are objected to because of the following informalities: the claims refer to effective field strength as measured in Joules (J), but the specification shows that field strength is measured in Volts per centimeter (V/Cm). The examiner suggests changing "effective field strength" to --energy--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 74, and 90-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 74 and 166, it is unclear whether “the electrode” refers to the first electrode or the second electrode.

Claims 74, and 166 each recite the limitation “the housing surrounding the electrode” in lines 2-3. There is insufficient antecedent basis for this limitation in the claim and there is no recitation in claims 53 or 95 setting forth an electrode located on the housing.

With respect to claims 90-94, it is unclear how an ICD can comprise a first vector end point, a second vector end point, an origin, and a depolarization vector. The examiner understands a vector, a vector end point, and an origin to be mathematical expressions, rather than structural limitations. Furthermore, the angle of separation between the first and second electrode is indefinite because the angle would vary depending on the specific location in the heart chosen for the origin and would depend on the distance between the origin and the two electrodes. If the origin were chosen to be the right atrium, the angle of separation would be different from the angle of separation determined from an origin was chosen to be the left ventricle or right ventricle. If the electrodes were located further from the heart rather than closer to the heart, the angle would be larger. The examiner suggests utilizing an origin on the canister to describe a definite position of the first and second electrodes relative to one another.

Art Unit: 3762

Regarding claim 95, the language “. . . wherein the second electrode is positioned approximately 30 degrees to approximately 180 degrees, with respect to the patient's heart apart from the first electrode. . . ”is unclear since the particular angular position of the second electrode with respect to the patient's heart apart from the first electrode is indeterminate. The angle of separation between the first and second electrode would vary depending on the specific location of the reference point in/on the heart and the distance of the electrodes from the heart. If the reference point were chosen to be the right atrium, the angle of separation would be different from the angle of separation determined from a reference point located in the left ventricle or right ventricle. The examiner suggests utilizing a reference point on the canister to describe a definite position of the first and second electrodes relative to one another.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 53-54, 59-61, 63, 72, 75, 84-89 90, 95-96 101-103, 105, 114, 117-119, and 126-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,601,607).

With respect to claims 53, and 95, Adams shows an ICD comprising a housing (74); an electrical circuit (92) located within the housing; and a first electrode and a second electrode (CAN 32, SUB 34) coupled to the electrical circuit (Fig. 3).

Regarding claims 54, and 96, Adams shows at least a portion of the housing is non-planar (rounded edges of housing shown in Figs. 3-10).

Art Unit: 3762

With respect to claims 59-61, and 101-103, Adams shows the ICD can deliver monophasic, biphasic and multiphasic defibrillation waveforms (Figs. 11-12).

Regarding claims 63, and 105, Adams shows the first electrode (either CAN 32, SUB 34) can emit effective field strength for shocking the patient's heart.

With respect to claims 72, and 114, Adams shows at least a portion of the first electrode (CAN 32, 76, 84) is non-planar (Figs. 7-8).

Regarding claims 75 and 117, Adams shows the second electrode (CAN 32, 76, 84) is located on the housing (Figs. 3, 7-8).

With respect to claims 77, and 119, Adams shows the second electrode (SUB 34) is located on a lead (Fig. 3).

Regarding claim 90, Adams shows the position of first electrode and the second electrode are separated by an angle with respect to the heart (Fig. 3).

The functional language and statements of intended use ("for", "positioned") have been carefully considered but are not considered to impart any further structural limitations over the prior art.

9. Claims 53-54, 63, 70-72, 74-75, 77, 84-89, 90, 95-96, 105, 112-114, 117-119, and 126-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

With respect to claims 53, and 95, Hauser et al. shows an ICD comprising a housing (74); an electrical circuit (92) located within the housing; and a first electrode and a second electrode (28,29,62, 64,70, 82) coupled to the electrical circuit (Figs. 8, 11).

Regarding claims 54, and 96, Hauser et al. shows at least a portion of the housing is non-planar (rounded edges of housing shown in Figs. 8, 11).

Art Unit: 3762

Regarding claims 63, and 105, Hauser et al. shows the first electrode (62, 64, 70) can emit effective field strength for shocking the patient's heart.

With respect to claims 70-71, and 112-113, Hauser et al. shows the first electrode (62, 64, 70) can receive sensory information (Col. 7, lines 9-15).

Regarding claims 72, and 114, Hauser et al. shows at least a portion of the first electrode (62, 64, 70) is non-planar (Figs. 8, 11).

With respect to claim 74, Hauser et al. shows at least a portion of the housing is ceramic (Col. 6, lines 54-57).

Regarding claims 75 and 117, Hauser et al. shows the second electrode (62, 64, 70) is located on the housing (Figs. 8, 11).

With respect to claims 77, and 119, Hauser et al. shows the second electrode (28, 29) is located on a lead (Fig. 6).

Regarding claim 90, Hauser et al. shows the position of first electrode and the second electrode are separated by an angle with respect to the heart (Fig. 6).

With respect to claim 118, Hauser et al. shows the housing comprises a first electrode (70,62) located on a first end of the housing and a second electrode (70, 64) located on a second end of the housing (Figs. 8, 11).

The functional language and statements of intended use ("for", "positioned") have been carefully considered but are not considered to impart any further structural limitations over the prior art.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 55-58, 73, 78-83, 91-94, 97-100, 115, and 120-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607). Adams discloses the claimed invention except for the specific dimensions of the housing and first electrode, and the length of the lead. It would have been an obvious matter of design choice to size the length of the canister between approximately 3 cm to 30 cm long, approximately 5 cm to 20 cm long, or approximately 5 cm to 12 cm long; the depth of the canister to be less than 15 mm; and the area of the first electrode to be less than 1000 mm<sup>2</sup> or 2000 mm<sup>2</sup>; and the length of the lead to be approximately 5 cm to 55 cm, approximately 5 cm to 15 cm, approximately 15 cm to 25 cm, approximately 25 cm to 35 cm, approximately 35 cm to 45 cm, approximately 45 cm to 55 cm; the angle of separation between the first electrode and the second electrode with respect to the heart to be between approximately 30 and 90 degrees, approximately 90 and 120 degrees, approximately 120 and 150 degrees, approximately 150 and 180 degrees since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

12. Claims 55-58, 73, 78-83, 91-94, 97-100, 115, and 120-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. discloses the claimed invention except for the specific dimensions of the housing and first electrode, and the length of



Art Unit: 3762

the lead. It would have been an obvious matter of design choice to size the length of the canister between approximately 3 cm to 30 cm long, approximately 5 cm to 20 cm long, or approximately 5 cm to 12 cm long; the depth of the canister to be less than 15 mm; and the area of the first electrode to be less than 1000 mm<sup>2</sup> or 2000 mm<sup>2</sup>; and the length of the lead to be approximately 5 cm to 55 cm, approximately 5 cm to 15 cm, approximately 15 cm to 25 cm, approximately 25 cm to 35 cm, approximately 35 cm to 45 cm, approximately 45 cm to 55 cm; the angle of separation between the first electrode and the second electrode with respect to the heart to be between approximately 30 and 90 degrees, approximately 90 and 120 degrees, approximately 120 and 150 degrees, approximately 150 and 180 degrees since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

13. Claims 59-62, and 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Mouchawar (5,601,608). Adams discloses the claimed invention except for setting forth the specific waveforms utilized for defibrillation. Mouchawar teaches that monophasic and biphasic (multiphasic) defibrillation waveforms are well known (Figs. 5, 7, Col. 7, lines 12-58). Mouchawar also teaches that using a tri-phasic (multiphasic) charge balanced defibrillation waveform reduces post-shock block, and it was determined experimentally that the defibrillation threshold using a tri-phasic charge balanced defibrillation waveform was superior to the defibrillation threshold using conventional and charge balanced biphasic shocks (Col. 10, lines 45-67; Col. 11, lines 16-67). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser et al. to include the well known monophasic or biphasic (multiphasic)

Art Unit: 3762

defibrillation waveforms or the advantageous triphasic (multiphasic) charge balanced defibrillation waveform of Mouchawar in order to utilize well known defibrillation waveforms or to reduce post-shock block and utilize a waveform having a lower defibrillation threshold than conventional and charge balanced biphasic shocks.

14. Claims 62, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Mouchawar (5,601,608). Adams discloses the claimed invention except for setting forth the specific waveforms utilized for defibrillation. Mouchawar teaches that using a tri-phasic charge balanced defibrillation waveform reduces post-shock block, and it was determined experimentally that the defibrillation threshold using a tri-phasic charge balanced defibrillation waveform was superior to the defibrillation threshold using conventional and charge balanced biphasic shocks (Col. 10, lines 45-67; Col. 11, lines 16-67). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Adams to include the tri-phasic charge balanced defibrillation waveform of Mouchawar in order to reduce post-shock block and utilize a waveform having a lower threshold than conventional and charge balanced biphasic shocks.

15. Claims 64-69, and 106-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Ostroff (5,215,081). Adams is as explained before. Although Adams fails to specify the desirable shock energy for shocking the patient's heart, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the ranges of shock

Art Unit: 3762

energies set forth in the claims, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

16. Claims 64-69, and 106-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). and further in view of Ostroff (5,215,081). Hauser et al. is as explained before. Although Hauser et al. fails to specify the desirable shock energy for shocking the patient's heart, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the ranges of shock energies set forth in the claims, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

17. Claims 70-71 and 112-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Hauser et al. (5,385,574). Adams is as explained before. Although Adams fails to teach the first electrode (CAN 32) can receive sensory information, attention is directed to Hauser et al which teaches a similar device with housing electrodes that can either be used for defibrillation or sensing (Col. 7, lines 9-15). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to configure the defibrillation electrode of Adams to be able to receive sensory information as Hauser et al. teaches in order for the housing electrodes to be used interchangeably.

Art Unit: 3762

18. Claims 74 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Hassler et al. (5,470,345). Adams is as explained before. Although Adams fails to teach at least a portion of the housing is ceramic, attention is directed to Hassler et al. which teaches forming implantable medical devices from ceramic. Hassler teaches that the use of ceramics for the implantable medical device enclosure makes the enclosure transparent to RF waves for telemetry purposes. Hassler further teaches that metal enclosures often cause interference during telemetry (Col. 1, lines 19-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form at least a portion of the housing of Adams of ceramic as Hassler teaches in order to make the enclosure transparent to RF waves for telemetry purposes.

*Allowable Subject Matter*

19. Claim 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or suggest an ICD with a housing having a first electrode located on a first end of the housing and the second electrode located on the second end of the housing in combination with the second electrode being positioned substantially on the opposite side of the heart from the first electrode (located approximately 180° apart).

Art Unit: 3762

*Conclusion*

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. KenKnight (6,148,230) shows an ICD with an electrode and a lead with additional electrodes.

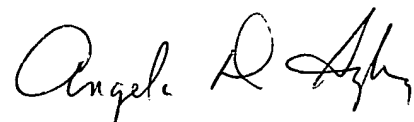
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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